Potential Nanomaterial Enhanced Conflicts

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Potential Nanomaterial Enhanced Conflicts

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Introduction and aim

Currently, no well-established and well-proved approach for predicted no effect concentration (PNEC) estimation is developed for nanomaterials (NMs) and regulators presently advocate for using the paradigm for traditional soluble chemicals, e.g. the Assessment Factor approach [1].

In short, the AF approach identifies the lowest effect concentration among the three trophic level base-set test organisms. An AF is applied, resulting in the PNEC. For environmental risk assessment (ERA) the predicted environmental concentration (PEC) is compared with the PNEC, where a ratio above 1 indicates potential negative impacts on the environment.

The aim of this work is to improve the framework for assessing NM effect studies for their adequacy for ERA.

Current evaluation of effect studies

The RA adequacy of NM effect studies are currently evaluated according to the Klimisch score K4-K1, which is a well-established evaluation approach of effect studies [2].

K4 is given a study, e.g. only reported in abstract form. K3 is given a study not properly reporting on experimental conditions. These two categories are not suited for RA.

K1 and K2 are given studies performed according to validated guideline test methods and preferably according to GLP and are thus adequate for RA without and with restrictions.

However, the Klimisch approach is not suited for evaluation of NM effect studies, as no guidelines addressing NM effect studies exist.

Key challenges of current framework

NMs are by nature particles, but the current RA framework is developed for soluble chemicals.

The current framework is based on a well characterized and steady exposure concentration. NM particles tend to dissolve and aggregate/agglomerate to various extends as time progresses. This results in an instable exposure, altered particle size distribution, surface area and surface charge. In fact, the tested NM is transformed during the test exposure duration.

The current framework favours studies performed according to validated guidelines and according to GLP. NM effect studies performed according to established guidelines will inevitably result in questionable results, but will be adequate for RA according to the Klimisch score.

PNEC from REACH and this study

Material	CAS#	PNEC, µg/L	Assessment factor	Approach
REACH				
AgCl	7761-88-8	0,04	3	SSD
Ag	7440-22-4	0,04	3	SSD
Ag-NP	7440-22-4	0,04	3	SSD
This study				
Ag-NP		0,001	1000	AF
REACH				
TiO_2	13463-67-7	127	100	AF
TiO_2-NP	13463-67-7	127	100	AF
Rutile	1317-80-2	127	100	AF
Anatase	1317-70-0	127	100	AF
This study				
TiO_2-NP		10	50	AF

Risk assessment adequacy for NM studies

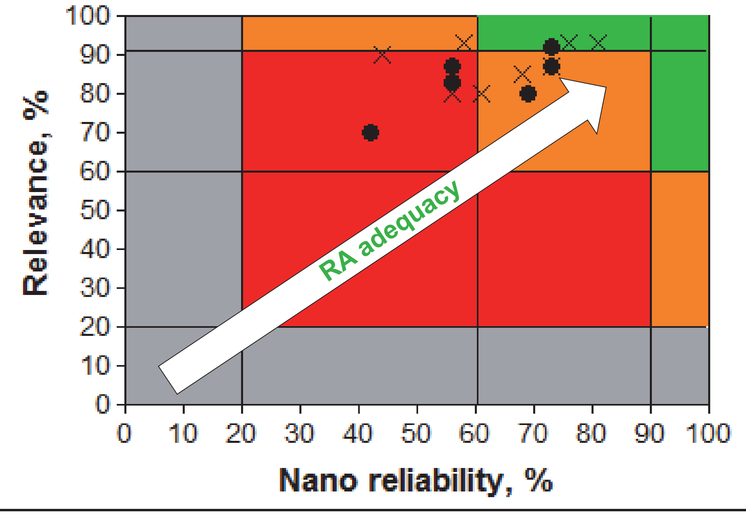
Stating the purity and basic identity (e.g. name, CAS #, coating) of the NM does not qualify for an adequate RA.

Ion release (solubility), surface charge, agglomeration, size distribution and concentration must be stated in stock suspensions, test medium or even better at the tested concentrations – preferable over the time course of the effect study.

As for other studies, relevant organisms, exposure, endpoints and life stage must be adequate.

Guideline and GLP do not disqualify a study, but do not automatically qualify for an adequate study. Rather studies planned, conducted and described scientifically sound are evaluated adequate for RA.

RA adequacy of NM effect studies [3]



Example for silver nanoparticles

Organism	T, h	Endpoint	C, µg/L	RA adequacy	Ref
D. rerio embryos	72	Notochord/control ≠	0,010	nRi3/Re2	[4]
D. rerio embryos	72	Hatching/control ≠	0,010	nRi3/Re2	[4]
P. subcapitata	96	Growth/EC_{50}	190	nRi2/Re2	[5]
D. pulex adults	48	Death/LC_{50}	40	nRi2/Re2	[5]
D. rerio juveniles	48	Death/LC_{50}	7200	nRi2/Re2	[5]
Nitrifying cultures	0,5	ROS/control ≠	100	nRi3/Re2	[6]
D. rerio embryos	72	Mortality/LC_{50}	≈ 30000	nRi3/Re2	[7]
D. rerio embryos	72	Notochord/$EC_{60\text{-}90}$	50000	nRi3/Re2	[7]
C. reinhardtii	5	Photosynthesis/EC_{50}	89	nRi2/Re2	[8]
V. fischeri	0,5	Lum inh/EC_{50}	420	nRi2/Re1	[9]
D. subspicatus	72	Growth/EC_{50}	34	nRi2/Re1	[9]
D. magna	48	Immobilisation/EC_{50}	1,2	nRi2/Re1	[9]
D. magna	48	Survival/LC50	2,75	nRi3/Re2	[10]

Example for titanium dioxide nanoparticles

Organism	T, h	Endpoint	C, µg/L	RA adequacy	Ref
D. magna	48	Mortality/EC_{10}	3700	nRi2/Re2	[11]
D. magna	504	Offspring/EC_{10}	5020	nRi2/Re2	[11]
D. magna	48	Mortality/EC_{50}	>20000000	nRi3/Re1	[12]
P. subcapitata	72	Growth/EC_{10}	3300	nRi2/Re1	[13]
P. subcapitata	72	Growth/EC_{50}	241000	nRi2/Re1	[13]
P. subcapitata	72	Growth/NOAEC	500	nRi2/Re2	[14]
P. subcapitata	72	Growth/EC_{50}	2530	nRi2/Re2	[14]
Chlorella	72	Growth/NOEC	890	nRi2/Re1	[15]
Scenedesmus	72	Growth/NOEC	1200	nRi2/Re1	[15]
P. subcapitata	72	Growth/NOEC	984	nRi3/Re1	[16]
D. magna	48	Survival/LC_{50}	7750	nRi3/Re2	[10]
C. dubia neonates	48	Death/LC_{50}	>10000	nRi2/Re2	[5]
D. rerio juveniles	48	Death/LC_{50}	>10000	nRi2/Re2	[5]

Conclusion

Despite similar endpoints are observed for the same organism, literature data show orders of magnitude in difference.

Putting emphasis on the scientific suitability of a NM effect study, shows that studies not performed according to guidelines can reveal data adequate for RA.

However, no evaluated study obtain the highest adequacy for RA, because not enough characterisation data for the tested NM exist.

References

[1] REACH (2008); [2] Klimisch et al. (1997); [3] Hartmann et al. (in prep); [4] Yeo and Kang (2008); [5] Griffitt et al. (2008); [6] Choi and Hu (2008); [7] Asharani et al. (2008); [8] Navarro et al. (2008); [9] Georgantzopoulou et al. (2013); [10] Das et al. (2013); [11] Wiench et al. (2009); [12] Heinlaan et al. (2008); [13] Hartmann et al. (2010); [14] Lee and An (2013); [15] Sadiq et al. (2011); [16] Aruoja et al. (2009)

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